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510(K) Summary

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Date Summary Prepared:	December, 14, 2010
Device Trade Name:	Smartxide 50 HS, Smartxide 50 MS
Common Name:	CO_2 Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX, 21 CFR 878.4810
Equivalent Devices:	Lumenis Acupulse30 ST/40 ST **(K082809)** DEKA Smart CO_2 with DOT scanner **(K072159)** Lumenis UltraPulse Surgitouch **(K030147)**
Device Description:	SmartXide 50 HS/MS is a surgical CO_2 laser with 50W of maximum power in continuous mode. The laser system is produced and sold with an internal predisposition for scanning system (HiScan Surgical for SmartXide HS, MiniScan Plus for SmartXide MS). Laser activation is by footswitch. Overall weight of the laser is 43 kg, and the size is 160 cm x 48 cm x 55 cm (H x W x D). Electrical requirement is 115VAC, 6A, 50-60 Hz, single phase. The wavelength of this laser is 10.600nm. This wavelength is mostly absorbed by water and that makes this laser particularly suitable for soft tissue surgery. The CO2 laser radiation is delivered to the treatment area through the handpiece. The handpiece is attached to the distal end of the articulated arm, which is a permanently mounted laser delivery system of the system. The articulated arm is an optical assembly that delivers free beam laser radiation. It is made up of seven mirrors placed on rotating knuckles: the mechanical accuracy of the articulated arm allows the CO2 laser beam to travel inside it and along its axis however the arm is oriented. The field of action of the articulated arm covers a radius of approximately 80 cm, the transfer efficiency of power is greater than 85%. The loss of 15% is balanced by a suitable calibration of the internal power meter. An air flow is provided by an internal pump in order to avoid dust and particles deposition on the optics during laser operations.

Emission parameters are selected on the front panel while emission activation is by the footswitch. The on-off switch and emergency switch are also located on the front panel of the system.
A warning light is located on the top cover, close to the control panel. Light ON state indicates that the system is enabled and ready.

The CO2 laser microsurgery is done with microspot micromanipulators and scanning systems. The CO2 laser focalized on very little spots (140-250μm) and moved by scanning systems is useful to fasten the surgical procedures and limit the thermal damage to the tissues surrounding the ablation. In the SmartXide 50 HS/MS series, the electronic controller of the scanner has been integrated in the laser system with touch screen settings.

The scanning systems move the beam on the tissue with controlled velocity and defined patterns to optimize the laser ablation. The high Power Density reached though little spots and typical of the cutting, are thus well controlled by the operator, and the tissue destruction happens in a very quick, delicate and precise way, reducing drastically the surgery time and limiting the lateral thermal damage and the negative phenomenon of carbonisation, with evident advantage for the patient and for the surgeon as well.

Both scanning units can be used together with Deka micromanipulator EasySpot.
Easyspot has a single ring nut rapid focalization system that allows to focalize the beam to the same focal length of the microscope and fix the position with a mechanical block. In this way the micromanipulator "remembers" the focus position, still allowing eventually the surgeon to defocus the beam from the same ring nut.
Thanks to its joystick, it is possible to regulate the mechanical tension and the maximum work field in order to easily control and never "loose" the beam even inside small size laryngoscopes.
On top of the joystick Easyspot can mount a remote control specially conceived to command top level scanning systems (HiScan Surgical). It allows the surgeon to have under direct control the more useful electronic scanning functions (rotation and dimension of the figures, scan off-scan on, centering) without moving his eyes from the microscope.

Intended Use:

The Smartxide 50 HS/MS system with its accessories is a medical device indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery and genitourinary surgery.

Comparison:

The Smartxide 50 HS/MS is substantially equivalent to the Lumenis Acupulse30 ST/40 ST **(K082809)**, to the DEKA Smart CO_2 (SmartXide, SmartUS20D) with DOT scanner **(K072159)** and to the Lumenis UltraPulse Surgitouch **(K030147)**.

	It has the same indication for use, the same principle of operation, the same wavelength and essentially the same power and pulse energy range as the predicate devices.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Conclusion:	The Smartxide 50 HS, Smartxide 50 MS lasers with delivery accessories are safe and effective devices for incision, excision, ablation, vaporization and coagulation of body soft tissue, including intraoral tissue.
Additional Information:	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Re: K101904
Trade/Device Name: SmartXide 50 HS/MS Laser with delivery accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: December 15, 2010
Received: December 17, 2010

Dear Mr. Peruzzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(K) Number (if known): K101904 pg 1 of 1

Device Name: SmartXide 50 HS/MS Laser with delivery accessories

Indications For Use:

The SmartXide 50 HS/MS system with its delivery accessories is a medical device indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in medical specialties including aesthetic (dermatology and plastic surgery), otolaryngology (ENT), gynaecology, neurosurgery and genitourinary surgery.

Prescriptive Use ✓ OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE NO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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